Conclusions: The treatment benefit of sodium bicarbonate is limited to small trials with extreme treatment effects, referred to as the small study effect. There does not appear to be any reduction in CIN in the large randomized trials. The small study effect is an important source of heterogeneity in meta-analyses and remains largely unrecognized.

TCT-329

A Randomized Controlled Trial for the Prevention of Contrast Induced Nephropathy with Sodium Bicarbonate vs. Sodium Chloride in Patients Undergoing Coronary Angiography: 2-year Results from the MEENA trial

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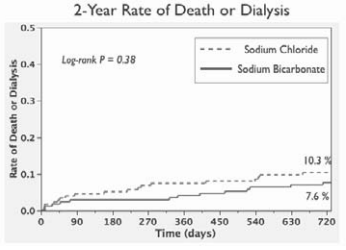
Background: Long-term clinical outcomes have not been previously reported from randomized trials of CIN prevention. We report 2-year results for all-cause mortality and need for dialysis from the randomized MEENA trial.
Methods: The MEENA trial was a randomized comparison of sodium chloride (0.9% normal saline) and sodium bicarbonate (150mEq of sodium bicarbonate in 1L of 5% dextrose) for the prevention of CIN in patients with stable renal insufficiency undergoing coronary angiography. All procedures were performed using ioxilan, a low-osmolar contrast medium. Patients received either fluid at the same rate: 3 mL/kg for 1hr before contrast exposure, and 1.5 mL/kg/hr during the procedure and for 4 hours afterwards. Inclusion criteria were: age >18 yrs with an eGFR (calculated using the MDRD equation) <=60 mL/min/1.73m2 and one or more of the following: age >75 yrs, diabetes mellitus, hypertension, or congestive heart failure (CHF). The primary endpoint was a 25% or greater decrease in estimated glomerular filtration rate on days 1-4 after contrast exposure.
Results: The median age of the cohort was 71 (interquartile range, 65-76) years, 45% had diabetes mellitus. The groups were well matched for baseline characteristics. As previously reported, there was no difference in the incidence of CIN between the groups: sodium bicarbonate, 13.3% vs. sodium chloride, 14.6% (P=0.82). 2-year follow-up was available for 98% of the subjects. A survival curve for death and dialysis using the Kaplan-Meier method is shown in the figure.



Conclusion: Rates of contrast nephropathy were similar between sodium bicarbonate and sodium chloride. Furthermore, 2-year rates of death or need for dialysis were also similar between groups.

TCT-330

Declining In-hospital Mortality Irrespective of Co-morbid Conditions In Patients Undergoing Coronary Bypass Surgery (CABG) in The United States

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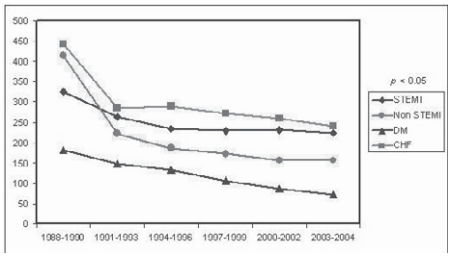
Background: Significant advances in surgical techniques and post surgical care have been made in the last ten years. The goal of this study was to evaluate any decline in the age adjusted in-hospital mortality rate of patients undergoing coronary artery bypass grafting (CABG) using a very large data base from 1989 to 2004 in the united state.
Method: Using Nationwide Inpatient Sample (NIS) data base, we obtained specific ICD-9-CM codes for CABG to compile the data. In order to exclude non-atherosclerotic cause of coronary disease, we used patients over the age of 40 years. We calculated total and age adjusted mortality rate per 100,000 for this period.
Results: The NIS database contained 1,145,285 patients who had CABG performed from 1988 to 2004. The mean age for these patients was 71.05 ± 9.20 years old. From 1989, the age-adjusted rate for all CABG related mortality has been decreasing steadily to reach the lowest level in 2004 [300.3 per 100.00 in 1989, (95%CI= 20.4-575.9) and 104.69 per 100,000 (95%CI=22.6-186.7) in 2004]. Total death also declined from 5.5 % to 3.06%. Despite increasing CABG performed in high risk patients with diabetes and congestive heart failure, this decline occurred irrespective of co-morbidities such as congestive heat failure, diabetes or acute myocardial infarction



Conclusion: The age adjusted in-hospital mortality from CABG has been declining steadily to the lowest level in 2004 irrespective of co-morbidities. This cause of this decline most likely reflects advancement in surgical techniques and post surgical care.

Innovative Devices and Futuristic Therapies

(Abstract Nos 331-335)

TCT-331

Robotically-Assisted PCI: First in Human Study

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Background: Current practice of percutaneous coronary intervention (PCI) is inconsistent, and includes physical risks for both patient (complication, radiation, contrast media) and operator (spine strain, accumulated radiation). Robotically-assisted PCI has a potential to decrease radiation exposure, contrast media usage and improved technical precision. The CorPath® 200 System (Corindus, Natick, MA) is a vascular robotic system that precisely drives coronary guidewires and stent/balloon catheters during PCI. The bedside unit consists of a cassette mounted on a robotic drive. The system is compatible and capable of advancing, retracting, and rotating 0.014" guidewires and rapid exchange catheter systems. The operator manipulates the interventional devices from a control console with joysticks while sitting comfortably at the radiation-shielded interventional cockpit.
Methods: A total of eight patients were enrolled in a single arm, open label, prospective study. All had evidence of myocardial ischemia, documented de novo coronary stenosis, and clinical indication for PCI. The primary endpoint was technical success (< 30% final diameter stenosis) after using the CorPath 200 system to deliver a balloon and a stent to the target lesion, and successfully retracting the devices without the occurrence of any in-hospital MACE (cardiac death, myocardial infarction, or clinically driven target vessel revascularization). Patients were followed for 30 days.
Results: All procedures were completed using the robotic system without any complications. All patients met the safety and technical success endpoint criteria. The CorPath 200 demonstrated a performance success of 97.8% in completing 48 procedural steps (47 out of 48). There were no instances of in-hospital or 30 days follow-up MACE or any other device or procedure-related adverse events. In 7/8 of the cases, the operators consistently scored the CorPath 200 performance as equal to manual operation. Compared to published data, average contrast media use was low (159 ml vs. 250 ml). The operator exposure to radiation was 97% lower than at the table position (1.8±1.9 μGy vs. 61.6±55 μGy, p<0.01).
Conclusions: Robotic PCI with the CorPath 200 system is safe and feasible. The operators could perform the procedures from a remote, radiation-protected control console. Initial experience with demonstrated procedural effectiveness was as good as manual PCI. The associated reduced contrast media volume may be related to better visualization and increased technical precision.

TCT-332

Furosemide-Induced Diuresis with Matched Hydration Compared to Standard Hydration for Prevention of Contrast-Induced Nephropathy. The MYTHOS Trial

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Purpose: Contrast-induced nephropathy (CIN) is a frequent cause of hospital-acquired acute kidney injury associated with increased short and long-term mortality. We investigated the effect of a new CIN preventive strategy based on a dedicated device (RenalGuard; PLC Medical System Inc., USA), capable of delivering i.v. fluid to a patient in an amount matched to urine volume increased by an i.v. bolus of furosemide. Aim of the study was to evaluate if furosemide-induced high-volume diuresis with concurrent maintenance of intravascular volume may prevent CIN.
Methods: The MYTHOS trial randomized 135 chronic kidney disease (CKD) patients undergoing elective or urgent PCI to matched hydration (RenalGuard group; n=63) or to i.v. standard saline hydration before and after PCI (control group; n=72). Matched fluid replacement was started ~90 minutes pre-PCI, maintained during and for up to 4 hours after PCI. Patients were given an initial i.v. bolus of 250 ml of normal saline over 30 minutes and then an i.v. bolus of furosemide (0.5 mg/kg). The RenalGuard automatically adjusts the i.v. saline infusion rate to precisely replace the measured urine volume output in real time. When >300 ml/hr urine output was obtained, patients underwent PCI. CIN was defined as a ≥0.5 mg/dl or ≥25% creatinine rise over baseline.
Results: Mean eGFR was 39±10 ml/min/1.73 m^2. Mean contrast volume was 191±111 ml in RenalGuard group and 212±113 ml in controls (P=0.28). In RenalGuard group, urine output ranged from 319 to 1788 ml/hr (mean 802±333 ml/hr). There were no serious device- or therapy-related complications. CIN occurred in 4 patients (6%) of the RenalGuard group and in 12 (17%) controls (P=0.06). A lower incidence of in-hospital MACE was also observed in RenalGuard patients (6% vs. 24%; P=0.008).
Conclusions: Furosemide-induced high urine output with maintenance of intravascular volume through matched hydration can be safely obtained with the RenalGuard system and may reduce the risk of CIN and associated adverse events in CKD patients undergoing PCI.

TCT-333

The Evolution Of Tavi: First Clinical Results Of The Second Generation Jenavalve Tavi System

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Intro: To evaluate feasibility, safety and valve performance in high risk patients (pat) with severe aortic stenosis JenaValve™ FIM-study was commenced in 2009.
Methods: 13 pat. were eligible and enrolled. 9 pat. underwent a successful procedure in which the JenaValve™ prosthesis was implanted correctly. One pat. withdrew from the study, and in 3 pat. the procedure was aborted, in one pat. due to a failed procedure (Type A dissection) and in 2 pat. due to unsuitable anatomy. Overall 9 pat. have been successfully treated in the FIM-study, all of them reached the primary endpoint of 30 days follow-up. 4 pat. achieved 3 months (mo.) follow-up, 3 pat. achieved 6 mo.follow-up. One patient died after 173days due to non valve related reasons while being at home. 12 mo.follow-up will be presented. None of the pat. required new onset pacemaker implantation.

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